PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2004/009605	29.03.2004	28.03.2003

International Patent Classification (IPC) or both national classification and IPC
A61M25/01, A61B18/14

Applicant
C.R. BARD, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2004/009605

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ in written format

   ☐ in computer readable form

   c. time of filing/furnishing:

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. II Priority

1. ☒ The following document has not been furnished:

   ☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

   ☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

   Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. ☐ It has not been possible to consider the validity of the priority claim because a copy of the priority document was not available to the ISA at the time that the search was conducted (Rule 17.1). This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

4. Additional observations, if necessary:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 28-37, 49-53, 38-48, 54-65

because:

☒ the said international application, or the said claims Nos. 28-37,49-53 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the whole application or for said claims Nos. 28-37, 49-53, 38-48, 54-65

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	☐	has not been furnished
	☐	does not comply with the standard
the computer readable form	☐	has not been furnished
	☐	does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☒ not paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

   see separate sheet

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-27

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	2-13, 16-27
	No:	Claims	1, 14, 15
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-27
Industrial applicability (IA)	Yes:	Claims	1-27
	No:	Claims	

2. Citations and explanations

   see separate sheet

Re Item III.

Claims 28-37 and 49-53 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

Re Item IV.

The separate inventions/groups of inventions are:

1-27
A catheter comprising a handle, a shaft portion coupled to a distal end of the handle, a tip portion, a braided conductive member coupled to the shaft portion and the tip portion, and a mandrel fixedly attached to the tip portion and slidably disposed within the shaft portion; wherein actuation of the mandrel expands the braided conductive member from an undeployed to a deployed position.
38-43
A catheter comprising a shaft portion coupled to a distal end of the handle. a tip portion, at least a portion of the tip portion being constructed of an elastomeric material, a braided conductive member coupled to the shaft portion and the tip portion.
44-48
A catheter comprising a handle, a shaft portion coupled to a distal end of the handle, a conductive member coupled to the shaft portion, the conductive member formed of a plurality of filaments, and a thermocouple wire coupled to a filament of the conductive member via a conductive junction, wherein the thermocouple wire is formed of a different material than the filament, and wherein the conductive junction is located between first and second ends of the filament.
54-58
A steering mechanism for a catheter, comprising a steering cable of first diameter, and an anchor disposed at a distal end of the steering cable, the anchor having a second diameter, wherein the first diameter is less than a diameter through which at least a portion of the steering cable passes and the second diameter is greater than the diameter of the lumen.
59-65
A method of controlling the rotational friction of a thumbwheel of a catheter handle,

comprising the rotational friction on the thumbwheel by compressing a spring that contacts the thumbwheel, and decreasing the frictional friction on the thumbwheel by decompressing the spring; and a handle for use with a catheter, the handle comprising a housing, a thumbwheel coupled to the housing, a spring coupled to the housing in contact with the thumbwheel, and means for increasing compression of the spring to increase rotational friction on the thumbwheel.

They are not so linked as to form a single general inventive concept (Rule 13.1 PCT) for the following reasons:

1. The closest state of the art document US5891136, cited in the research report, discloses a catheter with a handle, shaft, tip , braided conductive member and a mandrel.

2. The present application has nine independent claims:-
Claim 1 relates to a catheter with braided conductive member and a mandrel,
Claim 28 relates to a method of deployment (non-patentability),
Claim 38 relates to a catheter with a elastomeric tip and a braided conductive member,
Claim 44 relates to a catheter with a conductive member formed of filaments, and a thermocouple wire coupled to a filament,
Claim 49 relates to a method of using a catheter (non-patentability),
Claim 52 relates to a method of using a catheter (non-patentability),
Claim 54 relates to a steering mechanism for a catheter,
Claim 59 relates to a method of controlling the rotational friction of a thumbwheel, and
Claim 62 relates to handle for use with a catheter.

3. In the light of the closest prior art document, Claim 1 shows no special technical feature according to Rule 13.2 PCT. The first claim dependent on claim 1 to possess a special technical feature is claim 2, where the feature is the mandrel having two tiers with different diameters.

4. In the light of US5891136, independent claim 38 shows the special technical feature according to Rule 13.2 PCT of the elastomeric tip.

5. In the light of the closest prior art , independent claim 44 shows the special technical feature according to Rule 13.2 PCT of the coupling of the thermocouple wire to a filament.

6. Similarly, in the light of the closest prior art document, Claim 54 shows the special technical feature of the steering mechanism.

7. In the light of US5891136, independent claim 59 shows the special technical feature according to Rule 13.2 PCT of the controlling the rotational friction of a thumbwheel.

8. Similarly, independent claim 62 shows the special technical feature of a handle with a thumbwheel.

9. The special technical features of claim 1 (catheter with mandrel), independent claim 38 (elastomeric tip), independent claim 44 (thermocouple), independent claim 54 (steering mechanism) and independent claims 59 and 62 (handle with thumbwheel) show no common technical feature or inventive concept and are therefore considered to be five inventions.

Re Item V.

The following documents are referred to in this communication:

D1: US-A-5 891 136 (MCGEE DAVID ET AL) 6 April 1999 (1999-04-06)
D2: US-A-5 868 706 (COX DANIEL L) 9 February 1999 (1999-02-09)
D3: WO 94/00178 A (SCHNEIDER USA INC) 6 January 1994 (1994-01-06)
D4: US-A-5 681 280 (BOWE WADE A ET AL) 28 October 1997 (1997-10-28)
D5: WO 99/15225 A (UNITED STATES SURGICAL CORP ; FUTATO LISA D (US); ANGIORAD LLC (US); L) 1 April 1999 (1999-04-01)
D6: US-A-5 813 997 (QUIACHON DIGNAH B ET AL) 29 September 1998 (1998-09-29)
D7: WO 01/82814 A (BARD INC C R) 8 November 2001 (2001-11-08)

1. <u>Independent Claim 1</u>

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.
Document D1 discloses (the references in parenthesis applying to this document):

A catheter comprising:
a handle (handle 18);

a shaft portion (flexible catheter tube 12 with a proximal end 14 and a distal end 16) coupled to a distal end of the handle;
a tip portion (distal feature 66);
a braided conductive member (electrode structure 20, mesh structure 50) coupled to the shaft portion and the tip portion; and
a mandrel (stilette 76) fixedly attached to the tip portion and slidably disposed within the shaft portion;
wherein the actuation of the mandrel expands the braided conductive member from an undeployed to a deployed position
(see column 5, lines 35-52; column 10, lines 17-53; column 12, line 34 - column 13, line 13: column 24, line 5 - column 25, line 24 and Figures 1, 6-7, and 14).

2. Dependent Claims

Dependent claims 2-22, 27 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT).

2.1 The features of dependent claims 14 and 15 are already known from document D1.

2.2 The features of dependent claims 2 and 3 have already been employed for the same purpose in a similar catheter, see document D2, column 2, lines 41-44. It would therefore be obvious to the person skilled in the art, to apply these features with corresponding effect to a catheter according to document D1, thereby arriving at a catheter according to claims 2 and 3.

2.3 The features of dependent claims 4-10 and 20-22 have already been employed for the same purpose in a similar catheter, see document D3, page 3, line 33 - page 4, line 4; page 11, line 3 - page 12, line 27; page 16, line 5 - page 17, line 24; page 18, line 30 - page 19, line 2 and Figures 5-9. It would therefore be obvious to the person skilled in the art, to apply these features with corresponding effect to a catheter according to document D1, thereby arriving at a catheter according to claims 4-10 and 20-22.

2.4 In claim 11 a slight constructional change in the catheter of claim 10 is defined which comes within the scope of the customary practice followed by persons

skilled in the art, especially as the advantages thus achieved can readily be foreseen. Consequently, the subject-matter of claim 11 also lacks an inventive step.

2.5 In claim 12 a slight constructional change in the catheter of claim 7 is defined which comes within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen. Consequently, the subject-matter of claim 12 also lacks an inventive step.

2.6 The features of dependent claim 13 have already been employed for the same purpose in a similar catheter, see document D4, column 13, line 58- column15, line 18 and Figures 12-15. It would therefore be obvious to the person skilled in the art, to apply these features with corresponding effect to a D1 according to document D1, thereby arriving at a catheter according to claim 13.

2.7 The features of dependent claims 16, 17 and 27 have already been employed for the same purpose in a similar catheter, see document D5, page 6, line 15 - page 7, line 7. It would therefore be obvious to the person skilled in the art, to apply these features with corresponding effect to a catheter according to document D1, thereby arriving at a catheter according to claims 16, 17 and 27.

2.8 The features of dependent claims 18 and 19 have already been employed for the same purpose in a similar catheter, see document D6, column 11, lines 10-18. It would therefore be obvious to the person skilled in the art, to apply these features with corresponding effect to a catheter according to document D1, thereby arriving at a catheter according to claims 18 and 19.

2.9 In claims 23-26 a slight constructional change in the catheter of claim 1 is defined which comes within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen. Consequently, the subject-matter of claim 23-26 also lacks an inventive step.

3. Further Comments

3.1 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art

disclosed in the documents D1 and D7 is not mentioned in the description, nor are these documents identified therein.

3.2 "Incorporation by reference" is not an option in the European procedure; the description thus requires amendments in this respect on pages 1, 3 , 7 , 8 , 18 and 31 when entering the regional phase.

3.3 The units inches and French employed on pages 9, 37 and 46 are not recognized in international practice, contrary to the requirements of Rule 10.1(d) PCT.

3.4 The vague and imprecise statement in the description on page 51 implies that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity (Article 6 PCT) when used to interpret them.